In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-0544V

ELAINE LABOR,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: July 8, 2024

Laura Levenberg, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Colleen Clemons Hartley, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND DISMISSAL OF TABLE CLAIM[1]

On January 11, 2021, Elaine Labor filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Almost one year later, she filed an amended petition, containing additional detail and medical records citations. ECF No. 15. Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA"), a defined Table Injury, after receiving an influenza ("flu") vaccine on October 19, 2018. Amended Petition at 1, ¶¶ 2, 16.

[1] Because this Fact Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

For the reasons discussed below, a preponderance of the evidence supports the conclusion that Petitioner's pain onset occurred within 48 hours of vaccination, but that her pain was *not* limited to her left shoulder – meaning Petitioner cannot establish a Table SIRVA.[3] Any causation-in-fact version of the claim will only succeed if Petitioner can provide preponderant evidence of a vaccine-caused injury consistent with the symptom location determined in this Ruling. *See Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005) (setting out the three-pronged test which must be met to establish causation).

I. Relevant Procedural History

Along with the Petition, which set forth only the basic elements of her claim, Ms. Labor filed a signed declaration[4] from her counsel (labeled Exhibit 1) acknowledging the Petition had been filed without medical records (in an effort to get the case started before the then-proposed removal of SIRVA from the Vaccine Injury Table).[5] Exhibit 1 at ¶ 1. Over the subsequent year, Petitioner filed a signed declaration,[6] an amended petition, and the medical records required by the Vaccine Act. Exhibits 3-6, filed June 14, 2021, ECF No. 9; Exhibits 7-8, filed July 19, 2021, ECF Nos. 11, 13; Amended Petition, filed Dec. 15, 2021, ECF No. 15. On December 27, 2021, the case was activated and assigned to the "Special Processing Unit" (the "SPU" - OSM's adjudicatory system for resolution of cases deemed likely to settle). ECF No. 16.

On May 16, 2022, Petitioner conveyed her demand and supporting documentation to Respondent. Status Report, filed June 16, 2022, ECF No. 21. Approximately one month later, she filed updated medical records. Exhibit 9, filed July 11, 2022, ECF No. 22.

Because the case had been pending in SPU for more than a year without the Government's reaction to its viability, Petitioner filed a motion for a ruling on the record, asserting she had satisfied all requirements for a Table SIRVA plus the Vaccine Act's severity requirement. Petitioner's Motion for a Ruling on the Record ("Motion"), filed Jan. 4, 2023, at 5-8, ECF No. 26. After requesting additional time to file his response on several

[3] 42 C.F.R. § 100.3(c)(10)(ii) & (iii) (2017) (the second and third criterion listed in the Qualifications and Aids to Interpretation ("QAI") related to pain onset and symptom location).

[4] The declaration was signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 1.

[5] On July 20, 2020, the Secretary of Health and Human Services proposed the removal of SIRVA from the Vaccine Injury Table. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Proposed Rule, 85 Fed. Reg. 43794 (July 20, 2020). On April 22, 2021, the final rule removing SIRVA from the Vaccine Table was rescinded. National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, Withdrawal of Final Rule, 86 Fed. Reg. 21209 (Apr. 22, 2021).

[6] The declaration was signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 7.

occasions, Respondent stated that he was willing to engage in settlement discussions. Status Report, filed Feb. 20, 2023, ECF No. 30. The parties informed me they had reached an impasse in their settlement discussions 45 days later. Status Report, filed Apr. 6, 2023, ECF No. 34.

On May 23, 2023, Respondent filed his response, opposing entitlement. Respondent's Response to Motion, ECF No. 35. He argues that Petitioner has failed to satisfy two of the QAI requirements for a Table SIRVA: 1) pain onset within 48 hours of vaccination and 2) pain and ROM limited to the injured shoulder. *Id.* at 9-10; *see* 42 C.F.R. § 100.3(c)(10)(ii)-(iii). In her reply, filed one week later, Petitioner countered Respondent's arguments. Petitioner's Reply to Response ("Reply"), ECF No. 36.

II. Table SIRVA Claim

A. Legal Standards

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational)

B. Finding of Fact

I make these findings, related to onset and symptom location, after a complete review of the record to include all medical records, affidavits or declarations, and additional evidence filed. Specifically, I base the findings on the following evidence:

- Prior to vaccination, Petitioner suffered from hypertension; hypothyroidism; epilepsy; insomnia; back, bilateral knee, foot, and jaw pain; arthritis in her knees; and a compression fracture of the thoracic vertebra. *E.g.,* Exhibit 4 at 11; Exhibit 6 at 712. She previously had undergone a total left knee replacement in 2016, and continued to have issues with that knee, as well as her right knee. Exhibit 5 at 33-67; Exhibit 6 at 712.

- On October 19, 2018, Petitioner (66 years old) received the flu vaccine intramuscularly in her left arm during an appointment with her primary care provider ("PCP"). Exhibit 3.

- The morning of October 26, 2018, Petitioner called her PCP, stating that she "had her flu shot last Friday and she said she [wa]s still feeling pain in her arm and sometimes on her neck." Exhibit 6 at 702. Although she stated that she didn't want to come in person, she was informed that she needed to be evaluated. *Id.*

- At that visit during the afternoon of October 26th, Petitioner complained of "bilateral upper arm pain and shoulder/neck soreness since approx 10/22," adding that she had "rec'd flu vaccination 10/19." Exhibit 6 at 684. Noting that Petitioner's CPK[7] was "very mildly elevated," the nurse practitioner assessed Petitioner with muscle soreness. Exhibit 6 at 688. She instructed Petitioner to apply ice and heat, to provide an update on her condition next week, and to go to the emergency room if she experienced any acute change. *Id.*

- Three days later, on October 29, 2018, Petitioner returned to her PCP, again complaining of "pain in [her] bilateral arms and shoulders since getting [the] Flu Vaccination ten days ago." Exhibit 6 at 660. She reported being "unable to reach above her head." *Id.* Upon examination, she exhibited reduced range of motion ("ROM") in both shoulders, and testing revealed elevated CPK. *Id.* at 665. The PCP assessed Petitioner as suffering from muscle soreness and bilateral shoulder pain, stated that he suspected a rotator cuff tear. He referred Petitioner to an orthopedist, and ordered x-rays. *Id.* It appears that x-rays, which revealed mild degenerative changes, were taken only of Petitioner's left shoulder. *Id.* at 634.

[7] CPK stands for creatine phosphokinase. MEDICAL ABBREVIATIONS at 147 (16th ed. 2020). Creatine phosphokinase or creatine kinase "is an activated enzyme of the transferase class that catalyzes the phosphoryl of creatine by ATP to form phosphocreatine." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ("DORLAND'S") at 429 (32th ed. 2012). Phosphocreatine "is an important storage form of high-energy phosphate, the energy source for muscle contraction." DORLAND'S at 1437.

- At her next PCP appointment on November 12, 2018, Petitioner reported that she "continue[d] to have pain in the left arm at the site of the Flu Vaccine injection." Exhibit 6 at 624. The PCP ordered a CT scan of her left arm. *Id.* at 631.

- When she returned to her PCP approximately two weeks later, on November 26, 2018, Petitioner again "complain[] of left shoulder/bilateral shoulder soreness." Exhibit 6 at 601. It was noted that the results of the CT scan taken of her left arm were normal, except for mild degenerative changes. *Id.* at 601, 606. Reiterating his assessment, that Petitioner was suffering muscle soreness and bilateral shoulder pain, the PCP referred her to an orthopedist. *Id.* at 606.

- On January 10, 2019, Petitioner was seen by her neurologist for a follow-up of numbness in her right toes, her epilepsy, and a tremor that began two years ago. Exhibit 6 at 1098. There is no mention of Petitioner's shoulder pain in the record from this visit. *Id.* at 1098 - 1106.

- The next day, Petitioner visited the orthopedic department of her PCP clinic for evaluation. Exhibit 6 at 572-77. At this visit, she complained of "pain affecting her left shoulder and arm," that "occurred after receiving a flu shot in this left arm." *Id.* at 572. Stating that conservative measures "did not seem to help her pain," Petitioner reported experiencing "a fall when she tripped on a step at home, landing with her arm outwards" thereafter, which exacerbated her pain. *Id.* Diagnosed with sprain of the left rotator cuff capsule, bursitis, impingement syndrome, and primary osteoarthritis, Petitioner was administered a steroid injection and provided a home exercise program ("HEP"). *Id.* at 576.

- Less than two months later, on March 4, 2019, Petitioner returned to the orthopedic department for a reassessment of left shoulder pain. Exhibit 6 at 534. Reporting about four weeks of relief from the steroid injection and improved ROM from her HEP, Petitioner stated that she "continues to have pain on a daily basis." *Id.* At Petitioner's request, an MRI was ordered. *Id.* at 538.

- Unable to obtain the ordered MRI due to her aneurysm clips, Petitioner return to orthopedics on April 2, 2019. Exhibit 6 at 497. She also reported that she had not been performing her HEP, and had sustained a recent injury to her right foot and ankle. *Id.* The orthopedist administered a second

steroid injection and referred Petitioner to physical therapy ("PT") for her left shoulder, as well as her right foot and ankle. *Id.* at 500.

- On April 5, 2019, Petitioner visited her PCP for follow-up treatment of campylobacter enteritis,[8] dehydration, and a urinary tract infection contracted while on a cruise. Exhibit 6 at 486.

- At her initial PT evaluation, performed on April 10, 2019, Petitioner reported pain at a level of three to four and improvements in her ROM after the two steroid injections. Exhibit 6 at 465.

- On May 23, 2019, Petitioner was discharged from PT after attending only two sessions. Exhibit 6 at 448-49. It was noted that she had not attended PT for four weeks. *Id.* at 449.

- During the subsequent six months, Petitioner visited her PCP and neurologist on multiple occasions with no mention of left shoulder pain. Exhibit 6 at 178-447, 1089-97.

- On December 4, 2019, Petitioner sought treatment again from her PCP, reporting that "overall her shoulder is not as bad as it was previously, [that][s]he has some improvement with range of motion, although she has not regained full mobility, and [that] [s]he continues to have pain along the anterior deltoid region with range of motion." Exhibit 6 at 164. Petitioner acknowledged that she did not complete the full session of PT. *Id.* She was administered her third steroid injection. *Id.* at 167.

- In late December 2019, Petitioner sought treatment for continued symptoms in her left foot, thought to be connected to her earlier left foot injury. Exhibit 6 at 149. She was diagnosed with a left foot sprain, swelling, and an acute left fifth metatarsal shaft fracture. *Id.* at 152.

- On April 15, 2020, Petitioner tripped and fell on her right hand and wrist. Exhibit 6 at 56-60. While treated for that injury, she reported that "her shoulder technically [had]n't bother[ed] her for several months." *Id.* Admitting that she had not been performing her HEP, Petitioner stated that she continued to feel some sensitivity. *Id.*

[8] Campylobacter enteritis is "an intestinal infection by a species of Campylobacter; characteristics include diarrhea hat may be bloody, abdominal pain with cramps, and fever. The cause is usually ingestion of contaminated food or water." DORLAND'S at 624.

- Petitioner next sought treatment for left shoulder pain on December 15, 2020. Exhibit 9 at 479. Characterizing her left shoulder pain as a reoccurrence, she stated it had started approximately two weeks ago. *Id.* Petitioner was administered a steroid injection and provided with a topical Voltaren gel. *Id.* at 483-84.

- In her declaration, signed under penalty of perjury on July 19, 2021, Petitioner addressed only the basic requirements of the Vaccine Act. Exhibit 7.

On five occasions during the three month post-vaccination period, Petitioner complained of bilateral shoulder and neck pain that she attributed to her October 2018 vaccination. Exhibit 6 at 702, 684, 660, 624, 601. She consistently provided complaints supportive of an immediate pain onset, stating that she was *still* having pain (*id.* at 702), that her pain had begun *since* vaccination (*id.* at 660), and that she *continued* to have pain (*id.* at 624). Although provided by Petitioner, these close-in-time representations made for the purpose of obtaining medical treatment are still afforded great weight. *Cucuras*, 993 F.2d at 1528.

The only entry supportive of a later pain onset can be found in the record from Petitioner's afternoon visit to her PCP on November 26, 2018. At that visit, she reported bilateral upper arm, shoulder, and neck pain since approximately October 22nd, placing onset three days post-vaccination. Exhibit 6 at 684. Within this same record, it is correctly noted that Petitioner received the flu vaccine on October 19th. Although the specificity of this complaint, provided only seven days post-vaccination, would usually constituent strong evidence of onset, the probative value of this entry is significantly undermined by the inclusion of the qualifier "approx," meaning approximately. Thus, it alone is not sufficient to counter the compelling evidence offered by multiple entries, also provided close in time, that support a more immediate pain onset.

This same analysis applies to the multiple entries provided by Petitioner within three months of vaccination that include descriptions of pain in her neck and right shoulder. Although I credit Petitioner's argument – that the primary focus of the treatment Petitioner received remained her left arm/shoulder (Motion at 5-6; Reply at 3-4) - that fact does not distract from the premise that Petitioner suffered pain in these other areas as well.

Accordingly, I find preponderant evidence supports a finding that Petitioner's left shoulder pain began within 48 hours of vaccination, but also that she experienced pain in locations other than her left shoulder. Thus, Petitioner's Table claim is DISMISSED.

III. Potential for Off-Table Claim

A petitioner's failure to establish a Table injury does not necessarily constitute the end of a case under all circumstances, because she might well be able to establish a non-Table claim for either causation-in-fact or significant aggravation. *See Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274 (Fed. Cir. 2005); *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1357 (Fed. Cir. 2013) (citing *Loving v. Sec'y of Health & Hum. Servs.*, 86 Fed. Cl. 135, 144 (2009)).

Although she will need to provide evidence that accounts for symptoms she experienced, it is possible that Petitioner may be able to prove that the flu vaccine caused her symptoms or significantly aggravated her condition. And the three-day symptoms onset is still close enough to vaccination to constitute an appropriate time frame. However, Petitioner will need to provide this additional evidence to continue with her claim.

Formal resolution of this issue will likely require further review and most likely the retention of experts, which I am not inclined to authorize in the SPU. However, I will first allow the parties an additional 30 days to determine if an informal resolution can be reached. Thereafter, I will transfer the case out of SPU.

Conclusion

Petitioner has not established the onset of her left shoulder pain occurred within 48 hours of her receipt of the flu vaccine on October 19, 2018. **Accordingly, her Table SIRVA claim is dismissed.**

Because Petitioner *may* prevail on an off-Table claim, the parties should make one more attempt to reach an informal settlement in this case, before I reassign it out of SPU. **The parties shall file a joint status report indicating whether they believe an informal settlement could be reached in this case and updating me on their current efforts by no later than Friday, August 09, 2024**.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master